

AMENDMENTS

Please amend the above -identified application as follows:

In the claims:

Please cancel claims 9-12, and 23-38, without prejudice to renewal.

1. (Original) A method of producing a terminally sterilized topical patch preparation, said method comprising:
exposing a topical patch preparation to electron beam radiation for a period of time sufficient to terminally sterilize said topical patch preparation;
whereby a terminally sterilized topical patch preparation is produced.
2. (Original) The method of Claim 1, wherein said topical patch preparation is sealed in a packaging material containing an aluminum layer.
3. (Original) The method of Claim 2, wherein said sealed topical patch preparation is produced by:
 - (a) providing a topical patch preparation;
 - (b) packaging said topical patch preparation in packaging material comprising an aluminum layer; and
 - (c) sealing said packaged topical patch preparation.
4. (Original) The method of Claim 1, wherein said electron beam radiation is low level electron beam radiation.
5. (Original) The method of Claim 4, wherein said low level electron beam radiation ranges from about 5 to 19 kGy.
6. (Original) The method of Claim 4, wherein said low level electron beam radiation ranges from about 8 to 15 kGy.

7. (Original) The method of Claim 1, wherein said preparation is exposed for a period of time ranging from about 40 to 80 sec.

8. (Original) A method of producing a sealed, terminally sterilized topical patch preparation, said method comprising:

(a) producing a sealed topical patch preparation by the method comprising:

(i) providing a topical patch preparation;

(ii) packaging said topical patch preparation in packaging material comprising an aluminum layer; and

(iii) sealing said packaged topical patch preparation; and

(b) exposing said sealed topical patch preparation to low level electron beam radiation for a period of time sufficient to terminally sterilize said topical patch preparation;

whereby a sealed, terminally sterilized topical patch preparation is produced.

9-12 canceled.

13. (Original) A terminally sterilized topical patch preparation, said preparation comprising:

a fibrous material; and

an adhesive gel composition;

wherein said preparation contains nonviable microorganisms.

14. (Original) The preparation of Claim 13, wherein said adhesive gel composition comprises:

an active agent;

a water-soluble polymer gel;

water; and

a water holding agent.

15. (Original) The preparation of Claim 14, wherein said active agent is a local anesthetic.

16. (Original) The preparation of Claim 13, wherein said preparation is sealed in packaging material.

17. (Original) The preparation of Claim 16, wherein said packaging material comprises an aluminum layer.
18. (Original) The preparation of Claim 14, wherein said nonviable microorganisms are electron beam irradiated microorganisms.
19. (Original) A method of delivering an active agent to a subject, said method comprising: applying a terminally sterilized topical patch preparation comprising an active agent to a skin surface of said subject; whereby said active ingredient is delivered to a subject.
20. (Original) The method of Claim 19, wherein said preparation is the preparation of Claim 14.
21. (Original) A kit for use in transdermal delivery of an active agent to a subject in need thereof, said kit comprising:
- (a) a terminally sterilized topical patch preparation comprising an active agent; and
 - (b) instructions for using said preparation to practice the method of Claim 19.
22. (Original) A method of producing a terminally sterilized topical patch preparation, said method comprising: exposing a water-containing topical patch preparation to electron beam radiation for a period of time sufficient to terminally sterilize said topical patch preparation, to produce a terminally sterilized topical patch preparation.
- 23 - 38 canceled.